

## **REMARKS/ARGUMENTS**

The present Amendment is responsive to the final Office Action mailed May 28, 2008, in the above-identified application.

Claims 1, 2, 4, 7, 9-11, 15, 19 and 20 are currently pending in the present application.

Claims 1, 2, 11, 15 and 19 are amended to clarify features recited therein. Claims 2, 11, 15 and 19 are amended only for reasons of clarity and not patentability.

### ***Rejection of Claim 1 under 35 U.S.C. § 112***

Claim 1 was rejected under 35 U.S.C. 112, first paragraph, because the Examiner believes that specification does not provide enablement for the limitation of the pressure regulator self-regulating without direct pressure feedback. Applicants deleted this limitation from Claim 1 and respectfully submit that Claim 1 is now in compliance with 35 U.S.C. 112, first paragraph. Withdrawal of the rejection is respectfully requested.

### ***Rejection of Claims 1, 2, 4, 7, 9-11, 15, 19 and 20 under 35 U.S.C. § 103***

Claims 1, 2, 4, 7, 9-11, 15, 19 and 20 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Laing (CA 2,083,555) in view of Keime (GB 2,165,312). Reconsideration of this rejection is respectfully requested.

Claim 1 recites a pressure regulator positioned between the source of gas and the flexible bag. As recited in Claim 1, as amended, and disclosed in the original specification (see, page 6, lines 16-19), the pressure regulator self-regulates the pressure of the gas supplied from the source of gas such that this pressure of the supplied gas is maintained at a constant and predetermined level. In other words, the pressure regulator itself (i.e., without using any additional mechanism) maintains the constant and predetermined pressure of the supplied gas throughout dispensation of the liquid. Further, as a result of maintaining the pressure of the supplied gas at the constant and predetermined level, the pressure applied to the exterior walls of the flexible bag is also maintained at the constant and predetermined level.

Laing discloses a flexible bag 40 located inside a rigid housing 20 and a pressure pump 58 connected to an air bag 30 inside the housing 20 through a line 35. As air is supplied to the air

bag inside the housing, the air bag expands and applies pressure to the flexible bag 40 causing it to dispense fluid. As the fluid is dispensed from the bag 40 through an outlet line 45, the pressure of the dispensed fluid is monitored using an isolation device 60 connected to both the outlet line 45 and the pump 58. Laing teaches that when the fluid pressure in the outlet line 45 falls below a set level, isolation device 60 communicates with the pump 58 causing the pump to pump more air, thus, increasing the air pressure inside the air bag 30 and increasing the pressure on the flexible bag 40. See, Laing, page 12, line 25 - page 13, line 9 (emphasis added). Therefore, in Laing, the pressure of the air supplied from the pump is not maintained at the constant and predetermined level, as required by the amended Claim 1, and the pressure applied to the flexible bag is not maintained at the constant and predetermined level, as also required by the amended Claim 1. Accordingly, Laing does not disclose or suggest these limitations of Claim 1.

Keime does not remedy this deficiency of Laing. Specifically, Keime discloses a manually operable pressure injector in which, after a needle is introduced into a patient, the operator changes the pressure applied to the flexible bag 2 by manually operating the flow regulator 23 adjusting the flow of gas into the casing 1 containing the flexible bag (Keime, page 2, lines 76-85). The operator continually consults the pressure gauge 17 on the face of casing 1, which indicates the pressure in the inner space of the casing and adjusts the pressure during dispensation of the fluid using the flow regulator 23 (Keime, page 2, lines 20-22 and 81-90).

Accordingly, Keime does not disclose or suggest a pressure regulator maintaining the pressure of the supplied gas at the constant and predetermined level throughout dispensation of the fluid or a pressure regulator maintaining the pressure applied to the flexible bag at the constant and predetermined level throughout dispensation of the fluid, as required by the amended Claim 1. Moreover, as discussed above, a human operator operates the flow regulator 23 to control the pressure level. Therefore, the pressure regulator of Keime is not self-regulating.

In the Office Action, the Examiner argued that “Keime clearly suggests that the purpose of the pressure regulator and relief valve is to regulate the device at a constant and predetermined pressure.” Applicants respectfully disagree. Keime’s specifically teaches “building up” pressure

inside the case 1 (Keime, page 2, line 80), “draining off” pressure inside the case 1 (Keime, page 2, line 88) and “readjusting” the pressure (Keime, page 2, line 90) during the dispensation of the fluid from the flexible bag. Thus, Keime teaches away from the recitations of the amended Claim 1. Accordingly, even taken together in combination, Keime and Laing do not disclose or suggest the recitations of Claim 1.

Claims 2, 4, 7, 9-11, 15, 19 and 20 depend from Claim 1. Therefore, claims 2, 4, 7, 9-11, 15, 19 and 20 are allowable over the cited prior art at least for the same reasons as claim 1 and, further, on their own merits.

In view of the foregoing discussion, withdrawal of the rejections and allowance of the application are respectfully requested.

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RCF/AV:

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